

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 22 SEP 2005

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Applicant's or agent's file reference  STI-PCT-1	<b>FOR FURTHER ACTION</b>	See Form PCT/IPEA/416																								
International application No.  PCT/US04/36909	International filing date (day/month/year)  05 November 2004 (05.11.2004)	Priority date (day/month/year)  05 November 2003 (05.11.2003)																								
International Patent Classification (IPC) or national classification and IPC  IPC(7): G01N 31/00 and US Cl.: 422/56																										
Applicant  SEPARATION TECHNOLOGY, INC.																										
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p style="margin-left: 20px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 20px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) ___ , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"><input checked="" type="checkbox"/></td> <td style="width: 15%; text-align: left;">Box No. I</td> <td style="width: 70%; text-align: left;">Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>			<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand  03 June 2005	Date of completion of this report  19 August 2005 (19.08.2005)																									
Name and mailing address of the IPEA/ US  Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	<p>Authorized officer  Sam P. Siefke</p> <p style="text-align: right;">DEBORAH A. THOMAS PARALEGAL SPECIALIST GPO: 2009-0800</p>																									

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on translations from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:

- international search (under Rules 12.3 and 23.1(b))
- publication of the international application (under Rule 12.4)
- international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished

the description:

pages 1-20 as originally filed/furnished  
 pages\* NONE received by this Authority on \_\_\_\_\_  
 pages\* NONE received by this Authority on \_\_\_\_\_

the claims:

pages 21-26 as originally filed/furnished  
 pages\* NONE as amended (together with any statement) under Article 19  
 pages\* NONE received by this Authority on \_\_\_\_\_  
 pages\* NONE received by this Authority on \_\_\_\_\_

the drawings:

pages 1-10 as originally filed/furnished  
 pages\* NONE received by this Authority on \_\_\_\_\_  
 pages\* NONE received by this Authority on \_\_\_\_\_

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

- the description, pages \_\_\_\_\_
- the claims, Nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (*specify*): \_\_\_\_\_
- any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages \_\_\_\_\_
- the claims, Nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (*specify*): \_\_\_\_\_
- any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

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**Box No. IV Lack of unity of invention**

1.  In response to the invitation to restrict or pay additional fees the applicant has:
  - restricted the claims.
  - paid additional fees.
  - paid additional fees under protest.
  - neither restricted nor paid additional fees.
2.  This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
  - complied with.
  - not complied with for the following reasons:  
  

See the lack of unity section of the International Search Report (Form PCT/ISA/210)
4. Consequently, this report has been established in respect of the following parts of the international application:
  - all parts
  - the parts relating to claims Nos. 1-16

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N) **Claims** NONE **YES**  
**Claims** 1-16 **NO**

**Inventive Step (IS)** Claims NONE **YES**  
Claims 1-16 **NO**

## 2. Citations and Explanations (Rule 70.7)

**2. Citations and Explanations**

## Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

**V. 2. Citations and Explanations:**

Claims 1-16 lack novelty under PCT Article 33(2) as being anticipated by Lauks et al. (US 5,096,669). Lauks a system comprising a disposable device and hand held reader that performs a variety of electrochemical measurements on blood or other fluids. In operation, a fluid sample is drawn into the disposable device through an orifice by capillary action. The orifice is sealed off and the disposable device is inserted into the reader. The reader which controls the test sequence and flow of fluid causes a calibrant pouch located inside the device to be pierced, releasing the calibrant fluid to flow across the sensor arrays to perform calibration. Next an air bladder located in the device is depressed, forcing the sample across the sensors where measurements are performed and read by the reader which performs the calibrations. Once the measurements are made, the device can be withdrawn from the reader and discarded. The system 300 of the present invention comprises a self-contained disposable sensing device 10 and a reader 150. A fluid sample to be measured is drawn into device 10 and device 10 is inserted into the reader 150 through a slotted opening 360. The disposable device 10 contains sensing arrays 66 (FIG. 3) and several cavities 18, 20, 22 and conduits 220, 224, 228, 234 (FIGS. 2, 3, 4A and 4B) which perform sample collection, provide reagents for use in measurement and sensor calibration, and transport, fluids to and from the sensors. A sealed pouch 60 containing fluid to calibrate the sensors resides in the cavity 18 and a first conduit 220 (FIG. 2) leads from cavity 18. A second conduit 224 (FIGS. 2, 5) has an orifice 108 (FIG. 4B) at one end for the receipt of a fluid sample while the other end terminates at a capillary break 222. A third conduit 228 (FIG. 2) leads from the capillary break 222 past the sensing arrays 66 to a second cavity 20 which serves as a sink. The first conduit enters the third conduit between the capillary break and the sensing arrays. A third cavity 22 serves as an air bladder 229. When the air bladder 229 is depressed, air is forced down a fourth conduit 234 into the second conduit 224. In operation, a fluid sample is drawn into the second conduit 224 by capillary action by putting the orifice 108 at one end of the conduit 224 in contact with sample. After the sample fills the second conduit 224, the orifice 108 is sealed. Optionally, reagents may be mixed into the sample for testing. The reagent may be mixed into the sample by pouring the reagent into the second conduit through the orifice. The reagent may optionally be placed on an adhesive sheet which borders the conduits. Dry reagents may be placed in any of the cavities or conduits, or even in the sensor chamber, as appropriate for the measurements to be performed. The reagent pouch 60 is pierced by depressing the disc 102 down on the pouch 60 which causes pin 40 to pierce the other side of the pouch 60. The reagent in pouch 60 is chosen to suit the measurements to be performed; for simplicity of description, it will be assumed that a calibrant fluid is to be used to calibrate sensors prior to measurement, and that pouch 60 is filled with calibrant fluid. However, those skilled in the art will recognize that a calibrant will not be needed for all measurements, and that some measurements may require the presence of another aqueous reagent which may be conveniently stored in pouch 60. After the pouch is pierced, calibrant fluid flows from the cavity 18 through the first conduit 220 to the third conduit 228 and across the sensors 66 at which time the sensor calibration is performed. Next, the air bladder 229 is depressed forcing air down the fourth conduit 234 to one end of the second conduit 224 which forces the sample out the other end of the conduit 224, past the capillary break 222 and across the sensors where measurements are performed. As this is done, the calibration fluid is forced out of the third conduit 228 into the second cavity 20 where it is held. Third cavity 22 is defined in the interior surface of the lower housing member 12. This cavity 22 is used to store air and functions as an air bladder 229 that is formed when the adhesive sheet 74 is placed on the internal surface of the lower housing member sealing the cavity.

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**Supplemental Box**

Although the cavity 22 may be of any shape, it may conveniently be made rectangular. Sensing arrays 66 measure the specific chemical species in the fluid sample being tested. Preferably each of the sensing arrays comprises an array of conventional electrical contacts 70, an array of electrochemical sensors 68 and circuitry for connecting individual sensors to individual contacts. The electrochemical sensors 68 are exposed to and react with the fluid sample to be measured generating electrical potentials indicative of the measurements being performed. The electrical potentials are output on the electrical contacts 70 which connect to an electrical connector of reader 150 for the transmission of electrical potential values. The reader then performs the necessary calculations to display the concentration of the results of the measurement.